

Remarks

The above Amendments and these Remarks are in reply to the Office Action mailed December 12, 2005. No fee is due for the addition of any new claims.

Claims 1-6, 9-16, 18-19, 21, 23, 26-43 were pending in the Application prior to the outstanding Office Action. In the latest Office Action dated December 12, 2005 the Examiner rejected claims 1-6, 9-16, 18, 19, 21, 23 and 26-40 and objected to claims 41-43.

In the present Response the Applicant amends Claims 1, 21, 26 and 39-43, leaving for the Examiner's present consideration claims 1-6, 9-16, 18, 19, 21, 23 and 26-43. Reconsideration of the rejection is requested.

Yarrow Reference

The Examiner position is that the Yarrow device can be implanted. The Examiner does not explain the relevance of this statement.

The Applicant agrees that a Yarrow type device is intended to be implanted in a foot. However, the device would suffer as a spinal implant by "preventing any rotary movement about a vertical axis" and limiting movement to "lateral movement of the foot about a front to rear axis". In contrast, the Applicants invention would allow flexion, lateral, and extension bending between the first member and the spacer, which is not limited to flexion, lateral, and extension bending in only one plane.

Ferree Reference

The Examiner considered the declaration by the inventor to be ineffective to overcome the Ferree reference, US Patent Application Publication No. US 2004/0106998 (hereinafter Ferree).

The Applicant herein supplies a new declaration by Steve Mitchell. In the declaration, Mr. Steve Mitchell states that the declaration is made under 37 C.F.R. 1.131. (Mitchell declaration, ¶2). Mr. Mitchell states that he is an employee of St Francis Medical Technologies and specializes in spinal implant developments. (Mitchell declaration, ¶4). Mr. Mitchell, is the sole inventor of U.S. patent application 10/684,668. (Mitchell declaration, ¶5). Further, in the declaration, Mr. Mitchell declares under penalty of perjury that a prototype embodiment of the invention was shown on May, 2002 to an internal research and development team. (Mitchell declaration, ¶7). Mr. Mitchell declares Exhibits A and C are lateral anterior to posterior views of an artificial spinal prosthesis. (Mitchell declaration, ¶9). Mr. Mitchell declares Exhibits B and D are frontal anterior views of an artificial spinal prosthesis. (Mitchell declaration, ¶10). Mr. Mitchell declares that Exhibits A and C show the prototype implant described in the specification and shown in Figure 3 of the above application which incorporates the crossbar shown in Figures 2A-2D of the above application located between upper and lower plates inserted between two adjacent vertebrae of an artificial spinal prosthesis as represented in Figure 4 of the above application. (Mitchell declaration, ¶11). Mr. Mitchell also indicates that the invention was made in this country. (Mitchell declaration, ¶12). As such, the inventor is able to establish actual reduction to practice of this invention prior to the effective date of the Ferree reference. Therefore, the Applicant respectfully requests that the Examiner reconsider this rejection.

Claim 23

The Examiner's statement "the socket of the lower plate is parallel to the sagittal as shown in Figure 1G not parallel" does not make sense. The Examiner correctly notes that the socket is channel 160. The Examiner continues to believe that claim 23 was incorrectly drafted. The Examiner asks the question "Does Claim 23 directly conflict with Claim 43? The answer is No. The socket can lie either in the sagittal plane or the coronal plane. Claim 23 is supported in the specifications at least by Figure 1G which shows the "concave sockets is orientated to lie parallel to a sagittal plane of a patient" and by Figure 1E which shows the "concave socket is orientated to lie in a plane perpendicular to a sagittal plane of a patient". That is the socket can lie in the sagittal plane as in Figure 1G or the coronal plane as in Figure 1E. Both embodiments of the claimed subject matter are shown in the Figures. Thus, the claim language is supported in the specification.

Wagner Reference

The Examiner position is that the Wagner device is fully capable of being readjusted by the surgeon in a second procedure.

The Applicant points out that the Wagner device is a fusion device. The title of the patent is "Multi-Variable-Height FUSION Device" (emphasis added). The purpose of the device is to fuse vertebrae together in a set position. At the very least, Wagner teaches away from the concept that the device allows flexion, lateral, and extension bending.

The Applicant accepts the Examiner's argument that the previous amendments of Claims 1, 21, 26, 39 and 40 attempted to use function to distinguish over the cited references. The

Applicant has amended Claims 1, 21, 26, 39 and 40 incorporating non-functional language to emphasize the difference between the Wagner device and the Applicant's invention.

Pertinent Prior Art

The Applicant has considered Keller 2004/0153157 and Beaurain et al. 2004/0243240.

Allowable Subject Matter

The Applicant has amended Claims 41-43 incorporating the base claim as suggested by the Examiner.

Rejection under 35 USC 112 second paragraph

The Examiner repeats the statement "the socket of the lower plate is parallel to the sagittal as shown in Figure 1G not parallel". The Applicant requests a telephone interview with the Examiner to clarify this issue.

Rejection under 35 USC 102(b)

The Examiner rejects Claims 1-6, 9-14 and 19 under 35 USC 102(b) as being anticipated by Yarrow, US Patent No. 4,499,613 (hereinafter *Yarrow*). The Examiner states that *Yarrow* teaches an implant comprising a first piece having a first socket, a second piece having a second socket and a crossbar member that is at least partially received in the first socket and the second socket. The Examiner identifies a first bar as 46 and a second bar as 62. The Examiner further identifies the second socket 66 and 68. The Examiner does not identify the first socket.

The Applicant has amended Claim 1 with the limitation that “the crossbar comprises a first beam and a second beam, wherein the length of the second beam is configured transversely to the length of the first beam”. The amendment is supported in the specification at least at paragraphs [0032] and [0033]. In contrast, the *Yarrow* device does not have a crossbar made up of “a second beam, wherein the length of the second beam is configured transversely to the length of the first beam”. Thus, *Yarrow* does not disclose this element of claim 1. Claims 2-6, 9-16 and 18-19 properly depend on this limitation of Claim 1 and are believed patentable for at least the same reasons as independent Claim 1 and because of the additional limitations of these claims.

The Examiner is respectfully requested to reconsider the 35 USC 102(b) rejections.

Ferree reference

The Examiner considered the declaration by the inventor to be ineffective to overcome Ferree.

The Applicant supplies a new declaration from the inventor (as described in detail above). As such, the inventor is able to establish actual reduction to practice of this invention prior to the effective date of Ferree. Therefore, the Applicant respectfully requests that the Examiner reconsider this rejection.

Rejection under 35 USC 102(e)

The Examiner rejects Claims 1-6, 9-16, 18, 19 21, 23 and 26-40 under 35 USC 102(e) as being anticipated by Wagner et al., US Patent No. 6,706,070 (hereinafter *Wagner*). The Examiner directs the Applicant to look at all embodiments of his invention.

The Applicant believes that all embodiments of Wagner's invention have a common aim of fusing adjacent vertebrae so that they become immobile after the operation. We know this because Wagner tells us this in the patent title and at least three instances in the specification previously cited to the Examiner.

The Examiner's previous responses do not clearly identify the embodiment upon which the rejection is based. "In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application". MPEP 707.07(f). Further, "[t]he Examiner's action will be complete as to all matters ..." MPEP 707.07. Therefore, the Examiner is requested to provide a clear explanation of the rejection or otherwise to reconsider the ground for the rejection.

Claims 1-6, 9-16, 18 and 19

The Applicant has amended Claim 1 with the limitation that "a crossbar member comprising: a first beam; and a second beam, wherein the length of the second beam is configured transversely to the length of the first beam; wherein the crossbar is at least partially received in the first socket and the second socket, wherein at least the first piece does not fuse to the crossbar, wherein at least the first piece is capable of pivoting about the crossbar member to accommodate at least one of flexion, extension and lateral bending". The amendment to Claim 1 is supported in the specification at least at paragraphs [0037], [0039] and [0040].

As such Claim 1 can be distinguished from *Wagner* since the purpose of a fusion device is to fuse and therefore the *Wagner* device will fuse the crossbar. A surgeon who subsequently operated on a patient with a *Wagner* implant would necessarily have to remove calcium and

other fused matter from the device in order to make any adjustments. Thus, *Wagner* does not disclose this element of the claim. Claims 2-6, 9-16 and 18-19 properly depend on this limitation of Claim 1 and are believed patentable for at least the same reasons as independent Claim 1 and because of the additional limitations of these claims. The Examiner is requested to provide a clear explanation of the rejection or otherwise to reconsider the ground for the rejection.

Claims 21, 23, 37 and 38

Claim 21 recites “a crossbar member with a first beam that is received in the first concave socket of the upper implant and a second beam that is received in the second concave socket of the lower implant, wherein the length of the second beam is configured transversely to the length of the first beam, wherein at least one of the first piece and the second piece does not fuse to the crossbar, wherein at least one of the upper and lower implant is capable of pivoting about the crossbar” As such Claim 21 can be distinguished from *Wagner* since the purpose of a fusion device is to fuse and therefore the Wagner device will fuse the crossbar. Thus, *Wagner* does not disclose this element of Claim 21. Claims 23, 37 and 38 properly depend on this limitation of Claim 21 and are believed patentable for at least the same reasons as independent Claim 21 and because of the additional limitations of these claims.

Claims 26-34

Claim 26 recites “wherein the first beam is positioned in one of the socket of the upper plate and the socket of the lower plate, and the second beam is positioned in the other of the socket of the upper plate and the socket of the lower plate, wherein the length of the second beam is configured transversely to the length of the first beam, wherein at least one of the first

piece and the second piece does not fuse to the crossbar, wherein the implant remains able to accommodate at least one of flexion, extension and lateral bending” As such Claim 26 can be distinguished from *Wagner* since the purpose of a fusion device is to fuse and therefore the *Wagner* device will fuse the crossbar. Thus, *Wagner* does not disclose this element of Claim 26. Claims 27-34 properly depend on this limitation of Claim 26 and are believed patentable for at least the same reasons as independent Claim 21 and because of the additional limitations of these claims.

Claims 35, 36 and 39

Independent Claims 35 and 36 recite “wherein the rotation about the first axis is not limited to rotation in only one plane, wherein at least one of the first member and the second member does not fuse to the spacer”. Independent Claim 39 recites “wherein the bending between the first member and the spacer is not limited to bending in only one plane, wherein at least one of the first member and the second member does not fuse to the spacer”. As such Claims 35, 36 and 39 can be distinguished from *Wagner* since the purpose of a fusion device is to fuse and therefore the *Wagner* device will fuse the first member and the crossbar. Thus, *Wagner* does not disclose this element of Claims 35, 36 and 39.

Claim 40

Claim 40 recites “wherein the flexion, lateral, and extension bending between the first member and the spacer is not limited to flexion, lateral, and extension bending in only one plane, wherein the crossbar does not fuse to at least one of the first member and the second member” As such Claim 40 can be distinguished from *Wagner* since the purpose of a fusion device is to

fuse and therefore the *Wagner* device will fuse the crossbar. Thus, *Wagner* does not disclose this element of Claim 40.

The Examiner is requested to provide a clear explanation of each rejection or otherwise to reconsider the 35 USC 102(e) rejections.

Rejection based on 35USC §103

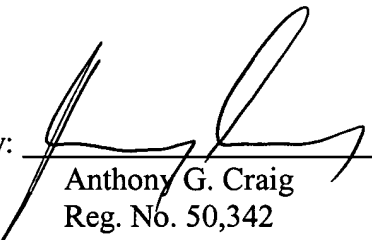
The Examiner rejects Claims 15-20 under 35 USC 103(a) as being patentable over Ferree in view of Marnay, PCT Application No. WO 01/01893 (hereinafter Marnay). As discussed above, the Applicant has shown that Ferree is neither anticipatory nor prior art to the Applicants invention and as such is not available to be combined with Marnay. The Applicant requests that the Examiner reconsider this ground of rejection.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

A check in the amount of \$200.00 is enclosed to cover the required fees. The Commissioner is authorized to charge any other necessary fees or any underpayment of fees or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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